ReadSensor

User's manual

Developped by 77 Elektronika KFT for UNISENSOR SA.

CHAPTER I.: SHORT NOTE

Rapid Designer - How to use - Short note

PRINTING MODE & PC MODE

The Readsensor can by used without PC and with PC.
To move from the use with or without PC you have to change the electronic key (photo nb 1) that is located just close to the printer paper under the bleu cap (photo nb 2). WHEN YOU CHANGE THE KEY PLEASE SWITCH-OFF THE READER.
There are 2 keys provided with the Readsensor: The first named “anyCheckValues” is for the use of the paper printer and the other key “camera” allows connexion of the readsensor to your PC. Both keys are placed into the small plastic pouch.

For using the paper printer, proceed as follow:

1. connect the small keyboard (photo nb 3).
2. connect to power supply (photo nb 3).
3. Switch-on (rear panel, photo 3) and after 2 sec the system ask for the name of operator. Introduce the name with the keyboard and press ENTER with the keyboard.
4. The system request to have a BLANK dipstick. Take the tray and deposit a blank dipstick into the furrow of the tray. The dipstick must facing out of the reader. The sample pad of the dipstick must be visible outside the reader when the dipstick is introduced. If the dipstick is in the wrong position, turn it for 180° like in the photo nb 4. IT IS VERY IMPORTANT TO INTRODUCE THE DIPSTICK IN THE RIGHT WAY THAT IS THE SAMPLE PAD ALWAYS OUTSIDE (facing out).
5. The system make the blank calibration automatically and than ask for the type of test you want to run. Switch on the black button from the reader to indicate the type of test and for running a Twinsensor, switch on the first black button just under TWIN.
6. The reader request to have a CHECK dipstick and you have to introduce the check lot number with the keyboard, so please type 051612 and ENTER.
7. Enter the EXP date that is 16/12/2006 and ENTER, note that the year should be in 4 numbers.
8. The reader ask you to pull the BLANK dipstick out and to insert a TWIN CHECK dipstick in. Remember the way to insert always the sample pad outside the reader (photo nb 4).
9. Now the system print a small ticket indicating that the blank and check have been done correctly. The reader is now free for any additional measurements. To continue please switch on “Measure” the first black button again.
10. Tell what you want to do for instance switch on START, again the first button.
11. Tell the type of test: again the first black for Twinsensor reading.
12. Inter the test code that is BT00640 ENTER with the keyboard.
13. Enter the LOT number in 6 numbers like 061303 ENTER.
14. Enter the EXP date like for the check EXP date : 13/03/2007 ENTER
15. Enter the SAMPLE ID: like MILK Nb1 ENTER
16. The reader ask you to pull the dipstick out, until you see the indication “Insert a dipstick” and than introduce it in the right position like on the photo nb 4.

    Than the system display and print the paper.

17. There is the result on the reader screen and if you want to screen all information print on “print-out” (second black button) again and again to see the list of information that were printed.

If you wish to continue the reader will keep in memory all information but you are always obliged to type the sample name or to leave it blank.

To do so, switch on START (first black button) and than on ENTER with the keyboard to accept what is on the screen, if you want to change you can change using the keyboard.

PHOT 1: Electronic key:

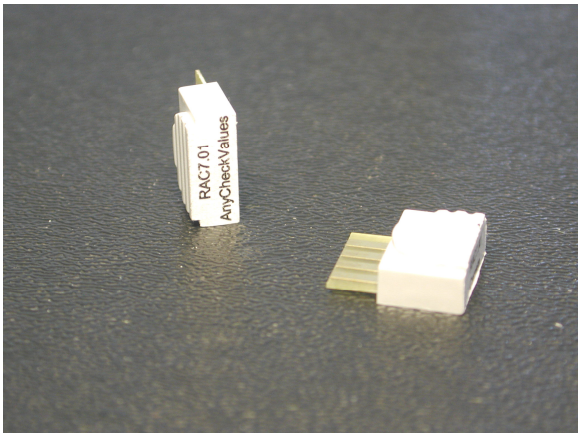


PHOTO 2 : Location of Electronic key:

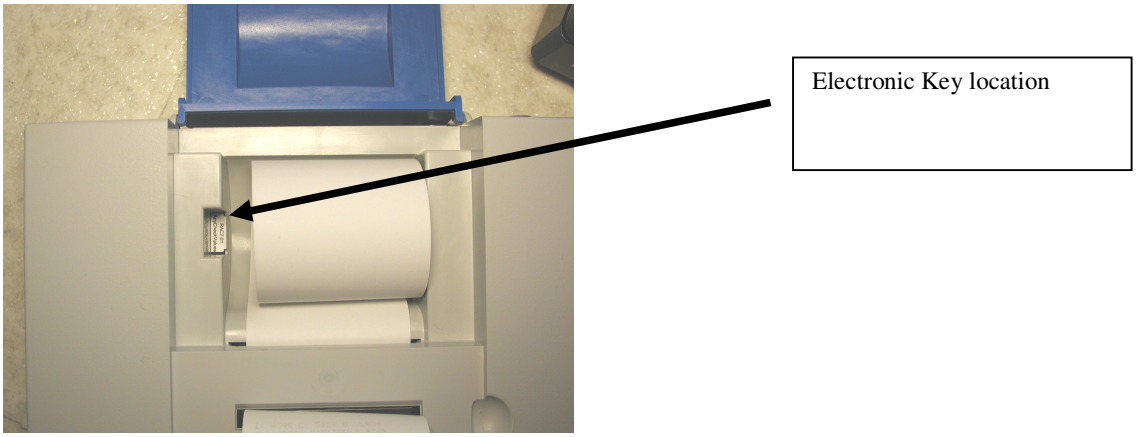
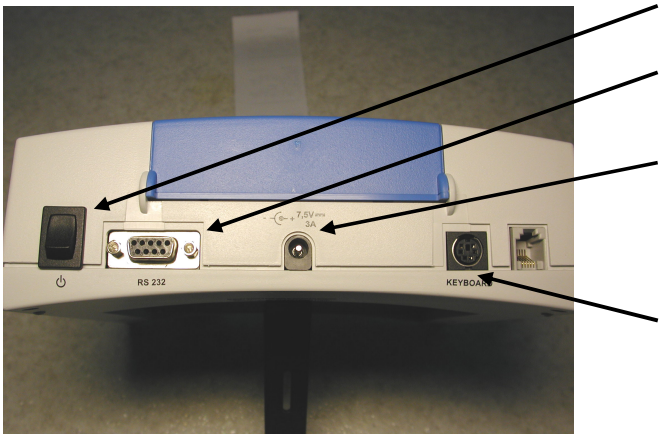


PHOTO 3: Rear panel of the Readsensor:



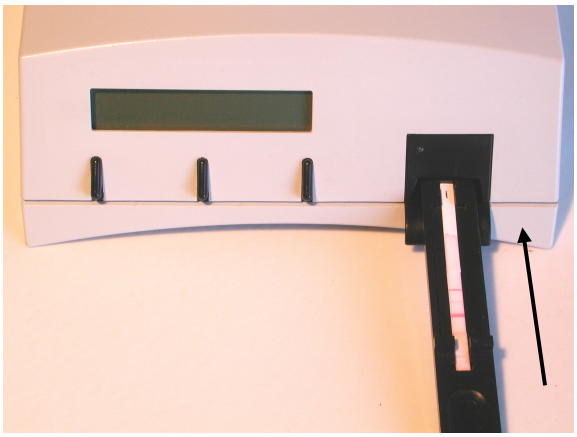
Switch-on/off button

Serial port to computer serial port

Power supply

Keyboard

PHOTO 4: Position of dipstick into the tray holder for the Readsensor.



Sample pad of dipstick always outside facing the operator.

The arrow indicates the direction to introduce the tray into the reader. The arrow indicates also the direction of the milk liquid running onto the dipstick.

TAKE CARE ON DIPSTICK POSITION IN THE TRAY HOLDER.
Dipstick must be "PLANNAR" and placed suitably in the groove of the black dipstick tray. Ensure that the lower edge of the dipstick (the edge which was in milk), is against the lower edge of the groove (the edge close to the part for holding the black tray).. If dipstick is badly positioned the reading can be disturbed.

For using with the computer, proceed as follow.

1. Switch-off the reader.
2. Open the blew cover and replace the electronic key by the "camera" electronic key.
3. Connect to computer with the serial cable.
4. Switch-on the reader.

Installation

Insert the CD and go to READSENSOR SOFTWARE 702, and start SETUP and follow the instructions to install the Rapid Designer program to your computer.
Connect the reader through its serial line to the serial port of your computer.
Start the Rapid Designer program and choose the proper serial port using the Ports section of the window.
Switch the reader on.

The Rapid Designer program

The program displays the image of the reader, together with the curve(s) which is (are) calculated based on it.
The curves are the integration of the pixel values in vertical direction. Only those pixels are used (and integrated) which are between the two horizontal red lines. So only that part of the image is used for any further processing (curve calculation, data saving) which are between the lines. The test and control line related data are displayed on the bottom side of the window. (position, tolerance, area, amplitude)

1. Change the test type

The radio buttons at the right bottom side of the Rapid Designer window could be used to choose the required type of test. When one of these buttons is clicked the reading will restart.

2. Taking white image (blank calibration)

Take a ”blank” image of the unused dipstick first. The *Normalized* values are calculated based on it.
Insert the unused dipstick into the reader. Wait while the full image is displayed and set the proper lighting. It can be done by clicking to the *Increase light* or *Decrease light* and displaying the white, blank curve (can be viewed by choosing *white* in the *View* section). The current light setting is displayed in the status row of the window (bottom). (e.g.: Lighting: 5)
The white curve should not reach the top of the diagram (because it means that saturation). Store the white curve by clicking the *Blank calibration* button on the bottom of the window. The white image can be displayed any time by choosing *White* in the *Picture* section.
Set also the start line, where the picture will start. It can be done by clicking the *Increase start ccd line* and *Decrease start ccd line*, next to the display field.
Store the lighting and start line by clicking the *Save lighting and lines* button.

3. Taking and analyzing images

The program refreshes the display and displays the actual image of the reader automatically if the *Actual* is set in the *Picture* section. It can be stopped and restarted by clicking on the *Stop* and *Start* buttons upper side of the window.

Teach the line position to the Reader:

Before doing any changes, please note the setting value of "position" and "tolerance" in order ot re-set whenever you want.
Line Position and Tolerance are set into the system but you can teach the line position at any time as follow:
Insert a used strip to the reader, and wait while the full image is displayed.

1. Select that line which would be set. It could be done by click on the little circle button in the proper line section on the bottom of the window. (Test line 2, Control line, Test line 1)
2. Clicking the left mouse button at the desired line position on the image of the strip (upper picture)
3. The line positions could be set in the other way. Write the desired line position in the desired line section (Test line 2, Control line, Test line 1) and press Enter.

Set the line tolerances:

Write the desired line tolerance in the desired line section (Test line 2, Control line, Test line 1) and press Enter.
When the position and the tolerance of the lines is set they could be saved by clicking the *Save lighting and lines* button.
The curves are displayed on the diagram section of the window. The following curves can be calculated and displayed:
White: the stored white/blank curve is displayed
Actual: the curve of the actual image
Normalized = (Actual/White)*100
If the *Clear* (in the bottom left corner) function is set, only the last selected curve is displayed. If it is not set, all the curves are displayed.

4. Save/Load data

Use the *Load* and *Save* data buttons on the upper left corner of the window. *Save* data button will store the picture of the cassette and the actual light and line settings. The *Load* button will display these data (picture, light and line settings).

It is practical if you use the *Continuous saving* button (this button is also in the upper left corner) in the Rapid Designer program to save the pictures and data.

1. Firstly write the number that how many measurement you would like to save to the little window at the right side of *Continuous saving* button.
2. Then click the Continuous saving button which will stay pressed state.
3. The program will only ask for the file name once, and then save the measurement serially while the set number become zero. So the program will take as many series measurement as you set in the little window on right of the *Continuous saving* button.
4. The program will save your data with the previous name but an increasing number will be added to the file name. (i.e.: *sample_006.rap*)
5. When this number becomes zero the continuous saving button will be unpressed state automatically but the series measurement could be stopped by click the *Continuous saving* button.

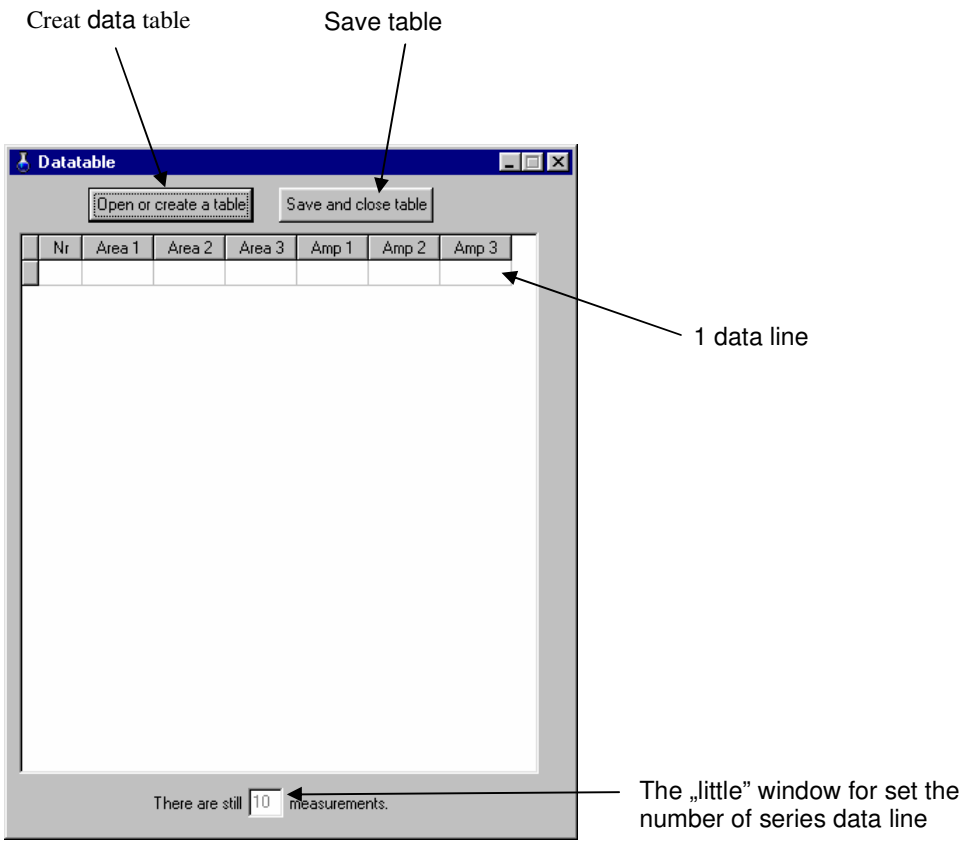
IMPORTANT! : When the moving line in the picture is not visible do not use the saving function!

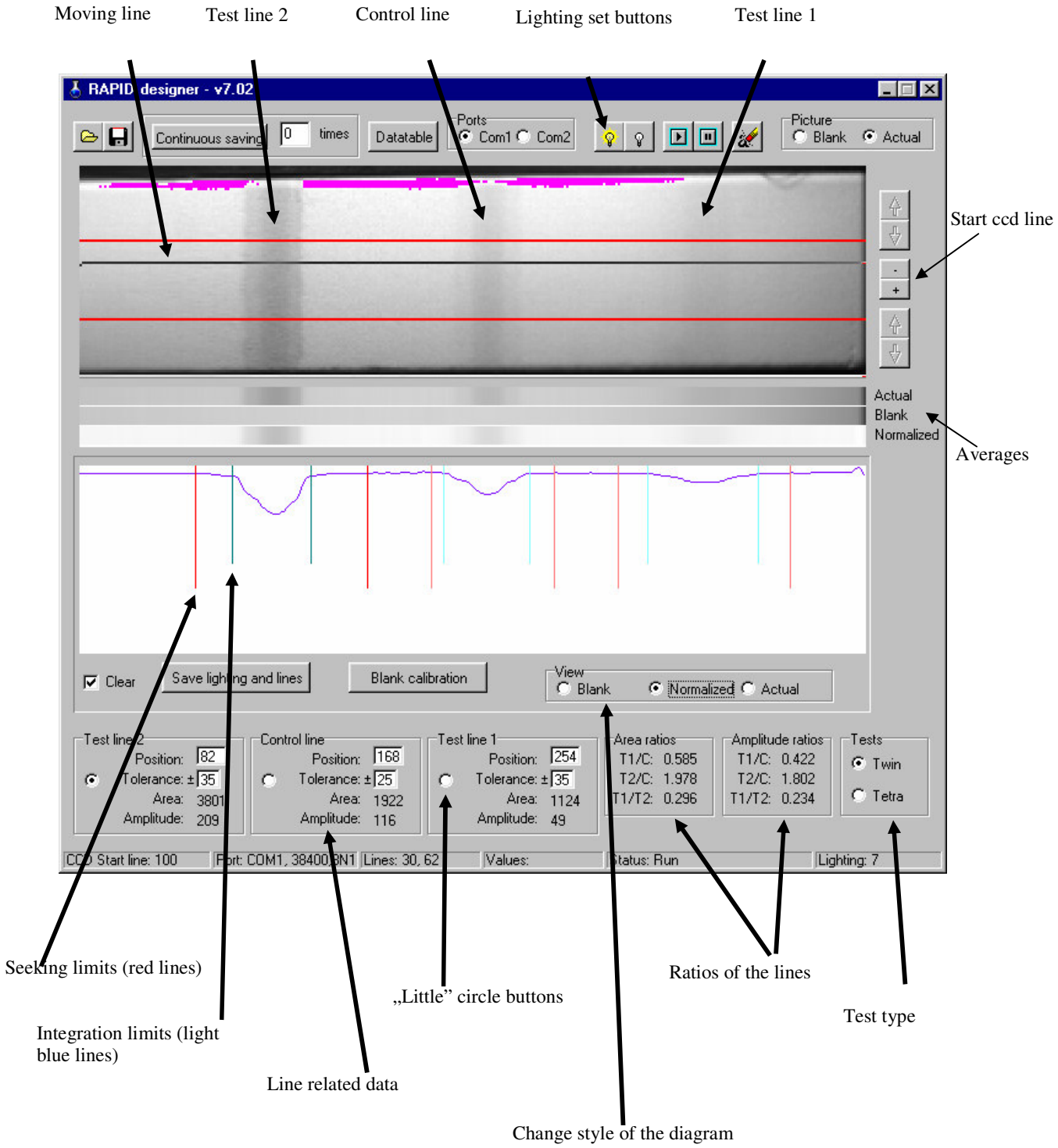
Database function:

If you click the *Datatable* button on the upper side of the Rapid Designer program an other window will appear. This is the data collector window which can open and save *.dbf* files.

1. Firstly a *.dbf* file need to be created or opened to start collect the data.
2. Click on the *Open or create a table* button then choose an exist *.dbf* file or write in a new name.
3. Now the program ready to collect data. (the 3 area and amplitude values)
4. The data line number which you want to collect could be set on the bottom side of the data table window. (The default values is 10) This little window works like at the Continuous saving function.
5. A new data line will be added to the data table when the picture comes up fully.
6. If the all data line which you set is collected the data table could be saved by click on *Save and close table* button.

The saved *.dbf* extension file could be opened in MS Excel for the further evaluating.




Moving line
Test line 2
Control line
Lighting set buttons
Test line 1
RAPID designer - v7.02
Continuous saving
times
Datatable
Ports
Com1
Com2
Picture
Blank
Actual
Start ccd line
Actual
Blank
Normalized
Averages
Clear
Save lighting and lines
Blank calibration
View
Blank
Normalized
Actual
Test line 2
Position: 82
Tolerance: ± 35
Area: 3801
Amplitude: 209
Control line
Position: 168
Tolerance: ± 25
Area: 1922
Amplitude: 116
Test line 1
Position: 254
Tolerance: ± 35
Area: 1124
Amplitude: 49
Area ratios
T1/C: 0.585
T2/C: 1.978
T1/T2: 0.296
Amplitude ratios
T1/C: 0.422
T2/C: 1.802
T1/T2: 0.234
Tests
Twin
Tetra
CCD Start line: 100
Port: COM1, 38400,8N1
Lines: 30, 62
Values:
Status: Run
Lighting: 7
Seeking limits (red lines)
Integration limits (light blue lines)
Line related data
„Little" circle buttons
Change style of the diagram
Ratios of the lines
Test type

CHAPTER II.: General User's manual

Version 1.2 - Pending the upgraded version.

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1 Introduction

Readsensor is a reflectance photometer designed to read and evaluate the appropriate Twinsensor (or Tetrasensor) dipsticks. The Twinsensor was designed for the safe and reliable detection of ß-lactams and tetracyclines compounds in milk with high sensitivity, (only tetracycline for the Tetrasensor), which is a key feature under the requirements of today's high standards in quality control systems. The Readsensor reads the dipsticks under standardized conditions, saves the results to memory and outputs them via its own inbuilt printer and/or serial (RS 232) interface.
This instrument is designed for In Vitro Diagnostic (IVD) use for professional use only.

BIOHAZARD: Treat all samples of animal origin as being potentially infectious. Always observe good laboratory practice.

Using Readsensor eliminates factors known to affect visual evaluation of test Dipsticks, such as:

- Objective readings especially in visually doubtful cases
- Different reaction time for the Dipsticks
- Automatic documentation for quality assurance purposes
- Clerical errors

2 System description

2.1 Twinsensor or Tetrasensor dipsticks.

Twinsensor (or Tetrasensor) dipsticks for the qualitative detection of total ß-lactams and tetracycline (or tetracycline) in food products. The Readsensor works only with these kind of dipsticks.
For professional use only.

INTENDED USE
The Twinsensor dipsticks are rapid chromatographic immunoassay for qualitative detection of Total ß-lactams and tetracycline in food products.
The Readsensor system will only indicates qualitative level of ß-lactams and tetracycline and should not be used as the sole criteria for concentration evaluation.

PRINCIPLE
The Twinsensor (or ,Tetrasensor) dipsticks are qualitative, nitrocellulose membrane based immunoassay for the detection of antibiotics in food products. The principle is described in each kit insert and can be obtained from the web site www.twinsensor.com and www.tetrasensor.com.

PRECAUTIONS:

- **Read the kit insert Manual carefully before installation so as to ensure proper operation of the analyzer from the outset.**
- **Do not use any components of the kits after expiration date.**
- **Do not eat, drink or smoke in the area where the specimens or kits are handled.**
- **Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.**

STORAGE AND STABILITY

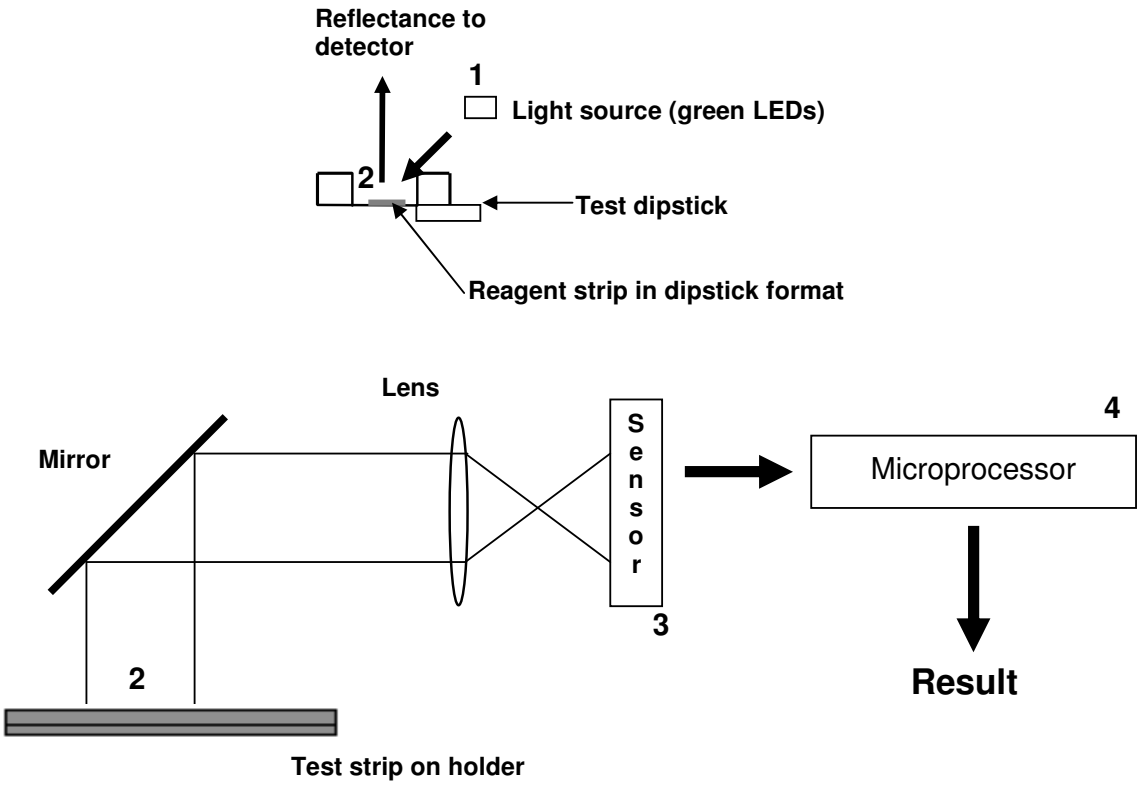
The kit can be stored refrigerated (2-8°C). The test device is stable through the expiration date printed on the label. The microwells and dipsticks must remain in their original sealed pouch or bottle until use.

WARNING: Do not freeze. Do not use beyond the expiration date.

2.2 Measuring principles

The Readsensor uses the incident light emitted by an internal light source reflected by the test strip surface as primary information. In other words the reader sees exactly the same thing as the human eye does, except the fact that the colour of the light source is adjusted to the spectral properties of the test strip in order to improve contrast and sensitivity. That is why green light is radiating from the insertion window during the measurement.

CAUTION: As the reader sees the same way as the human eye does, it is subject to the same interfering effects. No other object should be placed over the test strip before insertion. The surface of the strip should be plain, no bending of the strip is allowed. The surface must be free of scratches and other disturbing objects (drawing, writing, dust etc.). It is recommended to take care of the correct positioning of the strip, otherwise it going to give incorrect results.



The reflectance image is projected with an optic onto a CCD sensor, which resolves the picture into 320x90 pixels along the test strip. The optical density curve has a lower value in positions where the strip is dark and it has a higher value where the strip is close to white. The reader does all further processing on the resulting optical density curves.

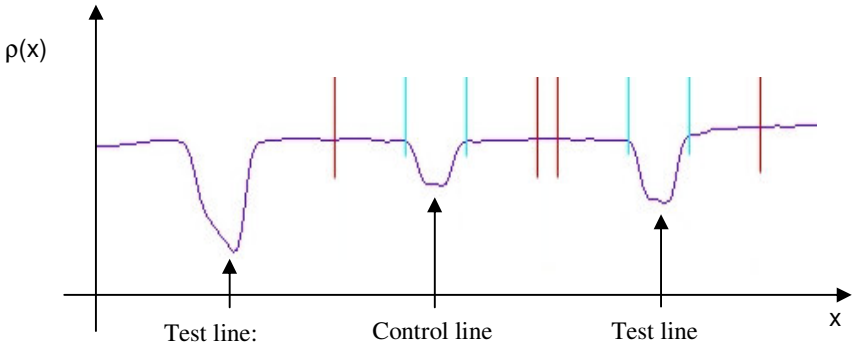
The user moves the dipstick under the LED reading head and the mirror. The analyzer reads the control, and the test lines on the dipstick. Reading is done electro-optically, as follows:
The LED (1) emits light of a defined wavelength on to the surface of the test pad (2) at an optimum angle. The light hitting the test zone is reflected more or less intensely depending on the darkness of the lines on dipstick, and is picked up by the detector through a mirror and a lens. The lens produces an upside-down image on surface of the CCD (3). The CCD consists of an A/D converter, and sends a digital electrical signal to CPU. Then the microprocessor (4) converts this digital reading to a relative reflectance lighting curve by referring it to a calibration standard (blank) lighting curve.
The reader calculates a ratio number from the integration area of the coloured lines on the test Dipstick surface.

Test dipstick is read photometrically after a lead (incubation) time. The CCD can see the entire surface of the test strip, but it is directed onto a 32 pixel wide zone of the relevant reaction area. The „footprint" of the optics – the area, which is projected onto the sensor array - is called the field of view (FOV).

The width of the dipstick is about 5mm and it is measured in the cross direction of the strip. The limits of the FOV are measured along the strip and are fixed for all Readers. The reader recognises the darkness and colour change only within the FOV.
The illumination of the test strip and the sensitivity of the CCD element are not uniform along the FOV and not constant in long term. Due to these facts the reader has to make a white calibration or blanking on a regular base. With the blanking procedure it is possible to equalize the non-uniformity of the optics as it is shown above. After a blank calibration a blank Dipstick is measured to have the same colour at each position.

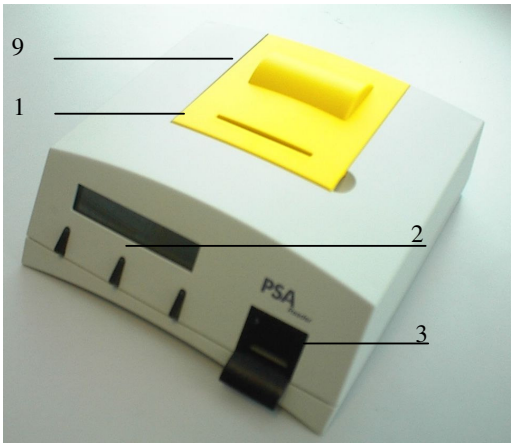
WARNING: The blank calibration procedure is essential for the proper operation of the ReadSensor that is why the operator is forced to repeat it regularly.

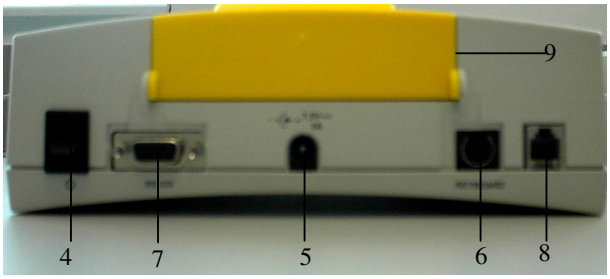
During real measurements, which may only happen after a blank calibration, the equalized optical density curve (relative reflectance curve) will look like shown below.



The evaluation of the Twinsensor or Tetrasensor dipstick is the following: There is a control line and two test lines on the dipstick of the Twinsensor and only one test line on the dipstick of the Tetrasensor. The reader calculates a ratio number from the integration area of these coloured lines on the reagent surface then compares this ratio with defined calibration curve range limits and outputs a qualitative result.
*The photometrical precision of the device remains below the precision of immunological measurements. The accuracy of the system derives from the dipstick. Please, refer to the User's Manual of the kit product for further information.

2.3 Components and Functions





Component	Function
1. Printer cover	Flips up for insertion of printer paper
2. Display/keypad	LCD display and three function keys for menu-driven operation and interfacing with the user
3. Test dipstick slot	Receives the dipstick tray
4. On/Off switch	Powers the unit on and off
5. Power socket	Socket used to connect the analyzer to the mains adapter
6. PS 2 socket	For connecting a PC keyboard
7. RS 232 interface	For connection to a personal or host computer
8. RJ 11/6 connector	Connector is used only in manufacturing or servicing
9. Program chip (key)	(under the printer cover) Contains the software needed to drive the analyzer, as well as the standard range limits

3 Software

3.1 Overview

The Readsensor software provides a user interface that enables all laboratory specific settings and recurrent functions to be selected via the liquid crystal display and function keys (see Sections 3.2 and 3.3).

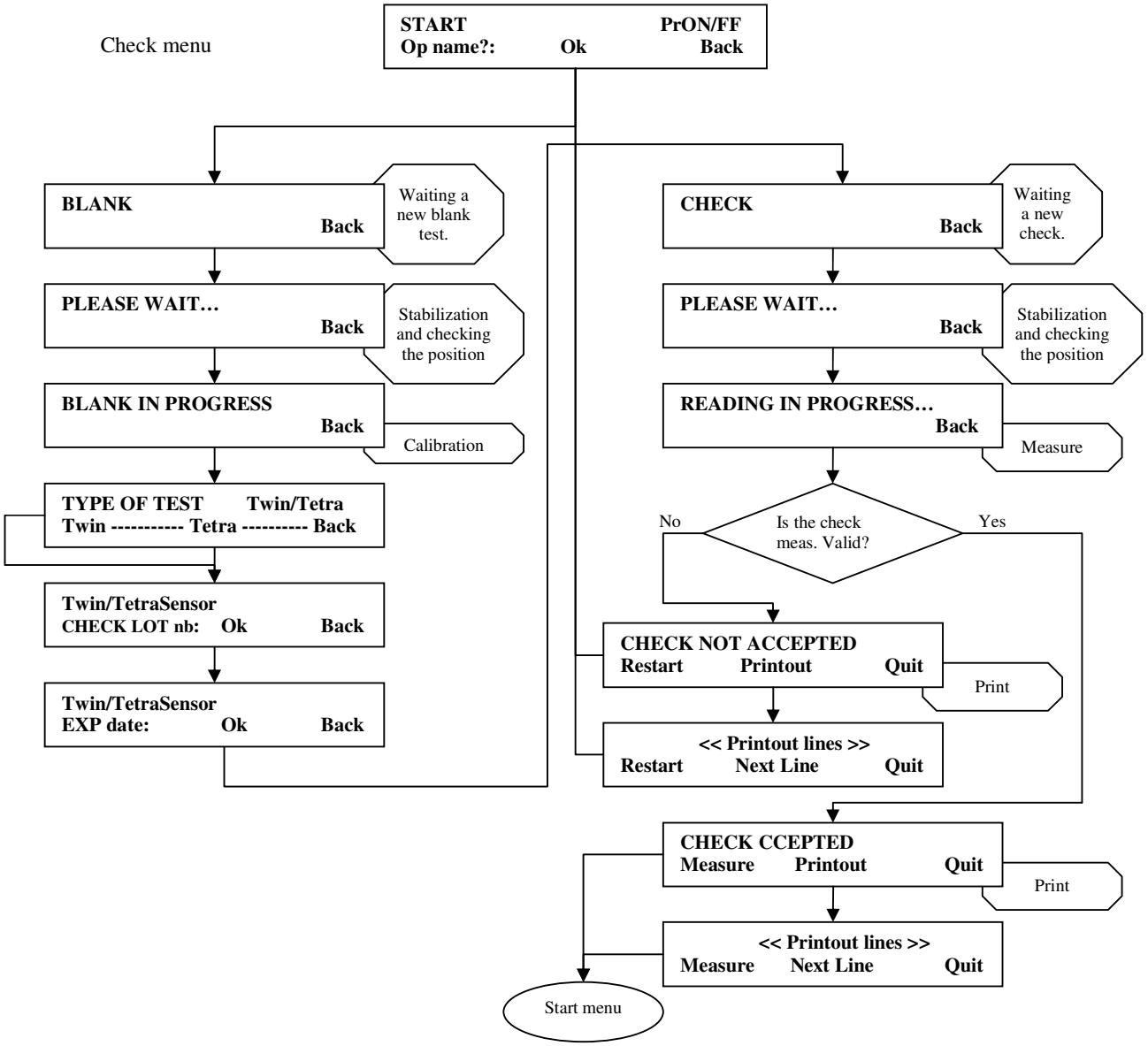
The three function keys assume the particular function displayed on the second line of the liquid crystal display. The first line of the display is used for system status and user information.

The user interface is self-explanatory, so that only details of the major functions are presented here.
Pressing the BACK button within any submenu to return to previous menu screen.

3.2 Menu Structure (Flowchart)

Have a look to the Readsensor screen menu

Check menu



Error messages:

E20: WRONG DATE

E25: EXTERNAL LIGHT
Next Quit

E04: WRONG CODEKEY

E21: WRONG TEST CODE

E28: BLANK / OPTIC FAULT
OK New Cal. Quit

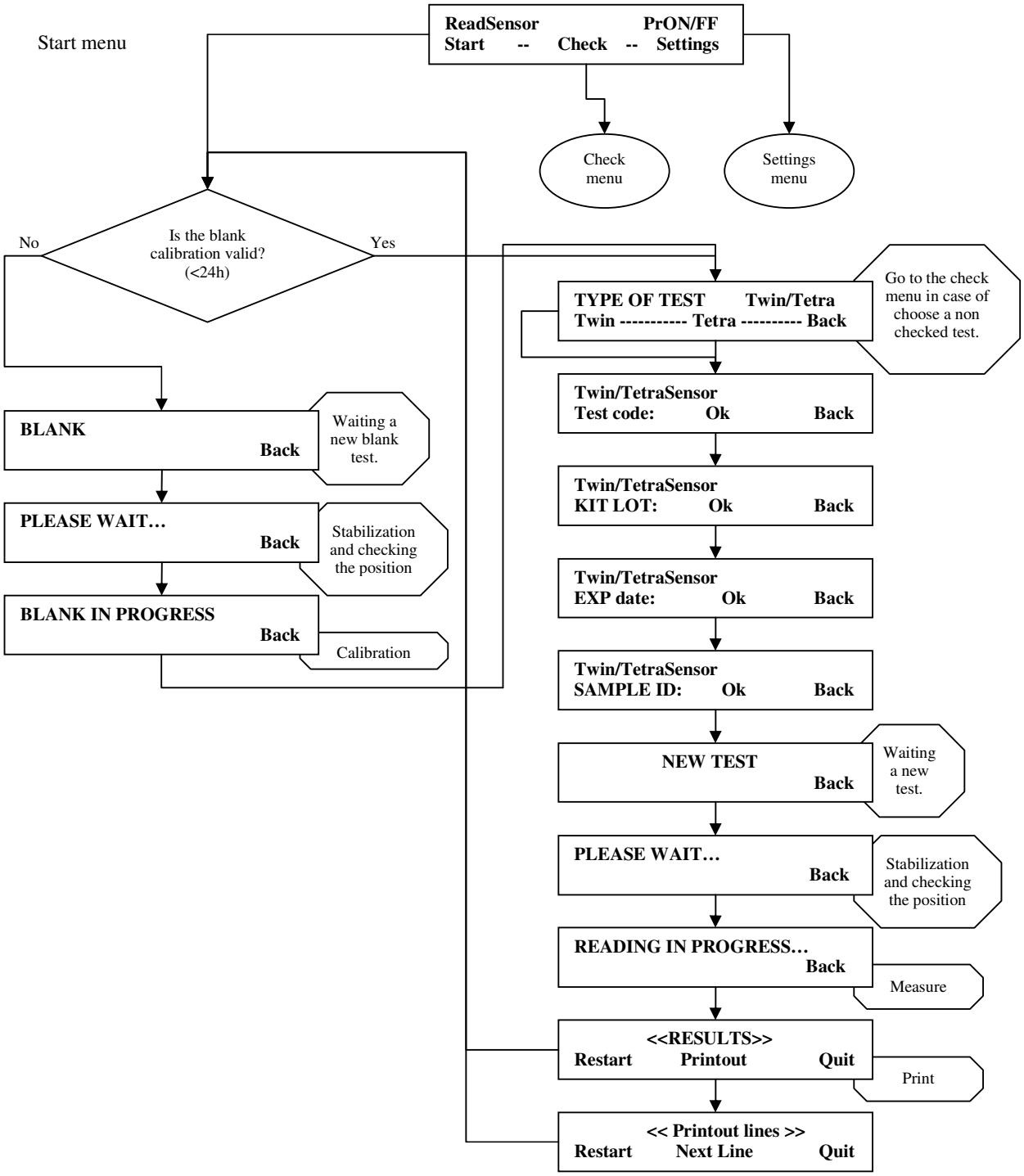
E05: NO CODEKEY

E22: CALIBRATION ERROR

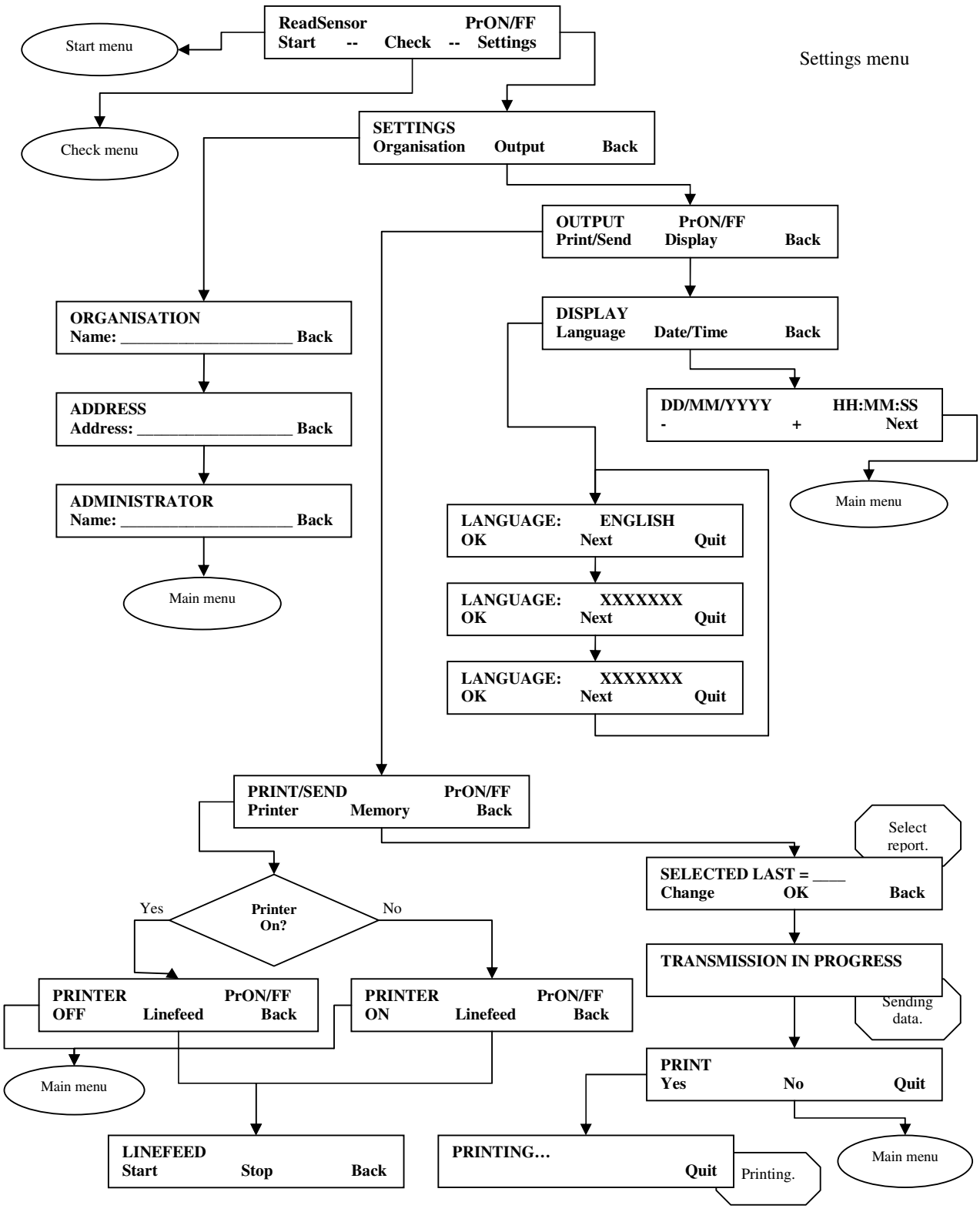
E30: WRONG FORMAT

E06: SAMPLE INVALID
Next Quit

E23: PRINTER ERROR
Quit


Start menu
ReadSensor PrON/FF
Start -- Check -- Settings
Check menu
Settings menu
No
Is the blank calibration valid? (<24h)
Yes
BLANK
Back
Waiting a new blank test.
PLEASE WAIT…
Back
Stabilization and checking the position
BLANK IN PROGRESS
Back
Calibration
TYPE OF TEST Twin/Tetra
Twin ---------- Tetra ---------- Back
Go to the check menu in case of choose a non checked test.
Twin/TetraSensor
Test code: Ok Back
Twin/TetraSensor
KIT LOT: Ok Back
Twin/TetraSensor
EXP date: Ok Back
Twin/TetraSensor
SAMPLE ID: Ok Back
NEW TEST
Back
Waiting a new test.
PLEASE WAIT…
Back
Stabilization and checking the position
READING IN PROGRESS…
Back
Measure
<<RESULTS>>
Restart Printout Quit
Print
<< Printout lines >>
Restart Next Line Quit

Settings menu



3.3 Readsensor Menu detailed description

The user can choose from the sub-menus by pressing buttons under the display. The current function of the pushbuttons is indicated right above on the display. To leave the current sub-menu and return to the Main Menu, press the **Quit** button. To return to the previous screen/menu press **Back** button.

Meas.
Starts the measurement.

Check
Run a check measurement.

Settings
The setting of the instrument.

3.3.1 The MEAS. menu
A routine measurement can be carried out under this menu.

Type of TEST
Select the type of test among Twinsensor TWIN or Tetrasensor TETRA.

Start
Measure with the actual Type of Test.

Back
Back to the main menu

Test code
Introduce the code of the kit in use that should looks like “AB12345”

Kit lot number
Introduce the kit lot number that is indicated on any kit labels and press ENTER with the keyboard. The number can be found in the packaging of the Dipstick. The number storages in the device after the first typing. If the number is invalid an error message will appear. If no keyboard is attached, the number can be given by the buttons of the devices.

Expiry date
Introduce the expiry date that is written on any kit labels. It must be in the following format DD/MM/YYYY .

OK
Accept the actually selected items.

BLANK STRIP
A non-used white strip is needed for blank calibration.
Insert a non-used Dipstick into the reader in order to carry out a blank calibration. Ensure the proper positioning of the strip. After insertion, the reader automatically recognises the strip and switches to a new screen.

Back
Stops the waiting for the non-used strip and return to the Meas. menubox.

PLEASE WAIT…
Check the fixed position of the blank Dipstick. That is important for the proper blank calibration. If it passed automatically switches to a new screen.
Back
Cancel the calibration and return to the Meas. menubox.

BLANK IN PROGRESS
The blank calibration.
As the reader recognised the non-used strip, it starts to carry out a calibration automatically. Wait until the next screen appears.
Back
Cancel the calibration and return to the previous screen.

BLANK TIME
The blank calibration is valid for twenty-four hours. Within this period, there is no need to carry out blank calibration again (except the Reader switch off or carry out a check measure).

SAMPLE ID:
Enter the sample ID to be tested.
Type the sample by using the keyboard. It can be 15 characters long (depending on the language setting). User can use alphanumerical characters Press <ENTER> on the keyboard to enter the name. The typed code/name/number will not remain to the next measuring cycle. The user has to type it in for every measurement. The reader accepts empty identifier field too.
OK
Accepts without any identifier. (OK will disappear if any key pressed on the keyboard)
Back
Cancel the modification of patient name and return to the Meas. menubox.

OK
Accepts without any identifier. (OK will disappear if any key pressed on the keyboard)
Back
Cancel the modification of birthday and return to the Meas. menubox.

NEW TEST!
Insert the strip to test into the reader. Ensure the proper positioning of the strip. After insertion, the reader automatically recognizes the strip and switches to a new screen.
Back
Stops the waiting for the test strip and return to the Meas. menubox.

PLEASE WAIT…
Check the fixed position of the test Dipstick. That is need for the proper reading of test. If it passed automatically switches to a new screen.
Back
Cancel the reading and return to the Meas. menubox.

READING IN PROGRESS
The reading and the evaluation of the test strip.
As the reader recognized the test strip, it starts to carry out the reading and the evaluation automatically. The evaluation is done based on the pre-defined test strip features.
It takes about 10 seconds after complete insertion.
Wait while the next screen appears.
Back
Cancel the reading and return to the previous screen.

RESULT:
The qualityative result is displayed.
Measure
Carry out a new measurement again.
Readout
The report printout can be displayed line by line. The first line is displayed and then the next display will appear.
Quit
Return to Main Menu

[printout line]
Displaying the lines of the report printout in the upper row of the display.
Measure
Carry out a new measurement again.
Next Line
Displays the next line of the printout report. At each button press the next line is displayed. After the last line the first one is displayed again.
Quit
Return to Main Menu

3.3.2 The SETTINGS menu
Setups and settings of the reader, reading memory recall / transfer and enter the user address can be done under this menu.

SETTINGS
User name or Administrator
Enter the user name administrator. It can be some information about the measuring place, person or other important things about the measure.(in five rows)

Output
Set the output features of the meter.

USER ADDRESS: (LINE *X*)
Write the *X* line of the user address. Number of the current line displayed on right side of the LCD's first line. Each row can be 20 characters.

Press <ENTER> on the keyboard to enter the current line. The equipment stores it after the switch off too.
↑
Return to the Settings menubox.

OUTPUT
Output features of the reader can be set under this sub-menu.
Print/Send
Printer settings and memory access for printing out and sending to a host PC.
Display
Display (date/time and language) settings.
Back
Return to the previous screen.

PRINT/SEND
Printer settings and memory access to printouts and sending to a host PC.
Printer
The online printing (reports are printed out immediately after the measurement) can be switched on or off.
Memory
Memory access for printing or sending.
Back
Return to the previous screen.

PRINTER PrON / PrOFF
The indicator is displayed according to the current setting on the upper right corner of the display.
OFF/ON
Alter the printer setting and return to the Main Menu.
(For switching off the printer when the printout of results is only required at the end of a series of readings (activated by the "Print/Send" function), or when results are to be sent via the interface to a personal computer or host only)
Linefeed
Feeds paper into the printer or causes paper to advance.
Back
Return to the previous screen.

LINEFEED
Paper forwarding control.
Start
Start the paper forwarding.
Stop
Stop the paper forwarding.
Quit
Return to Main Menu.

SELECTED LAST = *XX*
Select the number of reports to be printed out and sent to the PC.
Type the number in using the keyboard. The memory capacity of the reader is 26 reports, so the last 26 or less report will be printed out and sent. If the memory is full the automatically overwrite the oldest report. The details of sending to PC can be found in the chapter **PC CONNECTION**. Press <ENTER> on the keyboard or press

OK button to enter the number. If enter a greater number than the number of data blocks in the memory, it change to number of data blocks. The displayed number after entering this menu can be accepted and immediately send the dates to PC by pressing <ENTER> or **OK**

OK
Enter the number of the reports to be printed out and sent.

Back
Return to the previous screen.

PRINT
It can be chosen whether the reports should be printed too.

Yes
Print out the reports.

No
Do not print out the reports.

Quit
Return to Main Menu.

PRINTING
Printing is in progress.

Quit
Cancel printing and return to Main Menu.

DISPLAY
Display (date/time and language) settings.

Language
Language selection.

Date/Time
Date and time setting.

Back
Return to the previous screen.

dd/mm/yyyy HH:MM:SS
The currently set date and time are displayed. All fields can be set, from year to seconds.

+
Increase the current field.

-
Decrease the current field.

Next
Move the blinking cursor to the following field. After the last field, return to the main menu.

LANGUAGE:
For the moment the available language of the display and the report printouts is English.

OK
Select the currently displayed language.

Next
Skip to the next language.

Quit
Return to Main Menu without changing the current language setting.

3.3.3 CHECK menu

A check measurement can be carried out under this menu.

BLANK STRIP

A non-used white strip is needed for blank calibration.
Insert a non-used Dipstick into the reader in order to carry out a blank calibration. Ensure the proper positioning of the strip. After insertion, the reader automatically recognises the strip and switches to a new screen.

Back

Stops the waiting for the non-used strip and return to the Main menu.

PLEASE WAIT…

Check the fixed position of the blank Dipstick. That is important for the proper blank calibration. If it passed automatically switches to a new screen.

Back

Cancel the calibration and return to the Main menu.

BLANK IN PROGRESS

The blank calibration.
As the reader recognised the non-used strip, it starts to carry out a calibration automatically. Wait until the next screen appears.

Back

Cancel the calibration and return to the previous screen.

BLANK TIME

The blank time is not valid in check mode. Each check measure needs a blank calibration. But after the check measure it is not need in normal measure mode for twenty-four hours. Within this period, there is no need to carry out blank calibration again (except the Reader switch off/on or carry out a check measure).

PLEASE WAIT…

Check the fixed position of the check card. That is need for the proper reading of Dipstick. If it passed automatically switches to a new screen.

Back

Cancel the reading and return to the previous screen.

CHECK LOT nb:

Introduce the lot number of the Check dipsticks that are used.

READING IN PROGRESS

The reading and the evaluation of the test strip.
As the reader recognised the check Dipstick, it starts to carry out the reading and the evaluation automatically. The evaluation is done based on the pre-defined test Dipstick features.
It takes about 20 seconds after complete insertion.
Wait while the next screen appears.

Back

Cancel the reading and return to the previous screen.

4 Readsensor installation and quick start

WARNING: Read the Readsensor User's Manual carefully before installation so as to ensure proper operation of the analyser from the outset.

For a quick installation the following simple steps should be done:

- Refer to Short Note section: Installation on page 6.
- verify the hardware checklist
- checking for damage during transport
- connect the accessories and your PC to the reader according to your need
- make the initial basic settings on the reader

4.1 Hardware checklist

Upon receipt, check that the Readsensor box contains all of the following items:

- 1 Readsensor
- 1 Dipstick tray
- 1 AC Adapter
- 1 AC connecting cable for the adapter
- 1 roll of thermo printer paper
- 1 User's Manual

CAUTION: To ensure your readings are always accurate, do not set up Readsensor in close proximity to devices that create high-frequency fields, as they may interfere and produce false results. Such devices include, for instance, walkie-talkies, mobile telephones, microwave ovens and diathermic equipment.

ATTENTION: In the event of damage to goods during transit, contact your local representative.

ATTENTION: If your analyzer has been exposed to marked changes in temperature and/or humidity wait for it to acclimatize sufficiently before operating it.

4.2 Instrument connection

Power-on

(1) Unpack the Readsensor and place it on a stable, level surface. Do not expose the analyzer to direct sunlight or other source of direct light (for example a spot lamp).

(2) Connect the AC adapter to the power socket at the rear of the instrument and to an AC wall socket.

(3) Switch on the Readsensor using the on/off switch at the rear of the instrument.

(4) When all the elements are properly connected and the reader is plugged into the mains socket version information should appear first for 3 seconds followed by the Main Menu screen on the LCD. If you get an E05: NO CODEPIN error

message on the screen, please open the printer cover and check whether the code pin is properly placed in the nut on the left of the printer paper roll. The code pin should be sitting firmly in its position, if it is loose, insert it properly. This happens whenever the instrument is switched on. If an error occurs, consult the User's Manual or contact your local Readsensor representative.

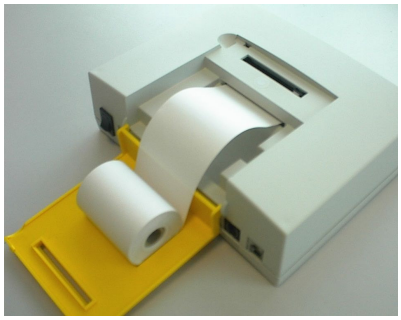
Basic initial settings before starting any measurement

Normally, there are three things to do before starting the first measurements.

- Insert a new paper roll if there is no paper in the printer
- Set the proper language
- Check the date and time

Paper insertion

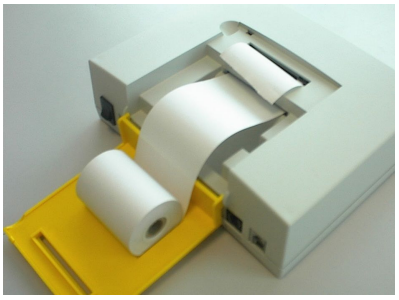
Flip open the printer cover of the instrument (instrument must be switched on). The paper roll is easily inserted if it is cleanly cut with a scissors. Hold the printer paper with the thermosensitive side facing downward and insert it into the lower printer slit.



Press the linefeed function key. The paper is automatically fed in. Let the printer proceed with the paper insertion until several centimetres are visible on the printer's output slit. Press the left function key "Stop", close the printer cover with one hand, and use the other hand to feed the paper in such a way that it protrudes above the printer cover and is not jammed. This avoids malfunctions.

ATTENTION: To remove the printed test report, tear off the paper by pulling it in front across the edge of the printer cover. The paper must protrude above the slit.

(5) In order to insert a new paper roll, first remove the eventual remaining piece of the previous roll. If necessary pull the paper out from the upper paper-out slit. **Reverse movement of the paper is not possible, forcing the wrong direction can lead to damage.** Take a new paper roll, cut off the adhesive tape if necessary and cut a clean, sharp edge for insertion. Open the printer cover and put the paper roll into its position. Take the edge of the paper and insert it horizontally into the paper-in slot. The smooth, shiny side (outer surface of the roll) should be facing down otherwise there won't be any normal printout. Using the user menu and the pushbuttons, enter the menu *Setting \ Output \ Print/Send*



\ *Printer* \ *Linefeed* \ *Start*. The printer should start forwarding blank lines on this action, the paper edge should be adjusted into the paper-in slit until the paper forwarding mechanism of the printer takes hold of it. When the paper length at the paper-out slot has reached about 2-3 cm press the *Stop* button for a second to finish the linefeed procedure. After this, close the printer cover so that the paper juts out through the printer cover's slit.

(6) To set the language of your choice, press the key sequence "Settings / Output / Display / Language" (see Sections 3.2 and 3.3).

(7) Press the key sequence "Settings / Output / Display / Date/Time" to set the proper date and time settings (see Menu Structure, Section 3.2).

(8) Readsensor leaves the factory with the default settings for Printer, Language and Date/time (see Menu Structure, Section 3.2). If your laboratory works differently, individual preferences can be entered via the menus.

Power-off

We recommend that the analyzer be switched off at the end of each working day and that the mains adapter be unplugged from the AC wall socket (see Section 7, Cleaning)

5 Check measure

Readsensor is calibrated before leaving the factory. When installed, it must be recalibrate with Check Dipstick before the first samples are read, and thereafter every hundredth measure. Check Dipstick strip has three check lines on it. That is standardized to give constant, defined reflectance readings. The purpose of the check measure is to verify for ageing effects, failure and infection of the optical system. Check lines on the check dipstick have exact area values, which required during the check measure. If the measured value is not in the limits the normal tests probably will not valid.

Procedure:
Press the middle function key ("CHECK") to carry out the Check measure.

1. Take a blank calibration(See section 6.1)

2. Remove a Check Dipstick from the Check Dipstick container. Be careful not to touch the check line surface and do not allow that those to come into infect with anything.

3. Insert the Check Dipstick, with the check lines facing upwards, to the Reader leading. Before calibrating, ensure that the Dipstick is clean and the strip is not scratched.

ATTENTION: It is very important that the Check Dipstick locks into the instrument correctly in order to ensure the quality of the calibration

4. As the reader recognised the Check Dipstick, it starts to carry out the reading and the evaluation automatically. Check line 1, 2 and check line 3 on the strip are read.

5. Check line areas are printed and displayed on LCD but is not stored in memory. Remove the Check Dipstick.

CAUTION: Regular Check measurement is necessary to ensure the quality of the results obtained. Unisensor SA. cannot warrant the correctness of results if the system is not checked regularly.

ATTENTION: You can make a Check measurement at any time, even if the one hundred measures have not elapsed since the last calibration, for example if a Readsensor Test Dipstick has returned an implausible result. Start the Check procedure by pressing the middle function key (“Check”) with the analyzer in main menu. Follow the calibration procedure described section “Check measure”.

Calibration errors
In case of an invalid check measure the equipment does not give any error messages.

6 Normal measure

6.1 Blank calibration

Readsensor is very easy to use. The first step of a measurement series is the blank calibration. This blank calibration is necessary for the equalization of the optics, for more details refer to the section **"2.2 Measuring principles"**. The blank calibration is valid for twenty-four hours. **The blank calibration should be performed with an unused, white and clean test.** The reader checks the correct positioning of the strip and the calibration will not be carried out with a not properly placed strip. **It is important to perform the calibration carefully because a wrong calibration might spoil all following measurements.**

If there is no valid calibration, the first time must carry out one. The reader will display *BLANK STRIP* and asks for a blank Dipstick for blank calibration. Insert a blank Dipstick into equipment. If the white test was already inserted, "<<PULL DIPSTICK OUT<<" message appear on LCD. The Dipstick has to be removed and reinserted, the reader does not accept any strip already residing in the optics at the start of any measurement. In the other case ">>PUSH DIPSTICK IN >>" message displayed on LCD. When the strip is accepted the reader will display *BLANK IN PROGRESS* in the first line. After it automatically set the lighting for the correct reading (it is the countdown on the LCD).

The purpose of calibrating the analyzer is to compensate for ageing effects that influence the optical system. If the compensation needed is excessive, for example because the test strip is badly soiled, or an LED is defective and cannot emit the required amount of light, an error message is displayed (see below).

Procedure

1. Tear off a normal Dipstick (The Dipstick must be totally blank and clear). Remove the Dipstick from the bottle. Be careful not to touch the surface of strip in the Dipstick and do not allow them to come into contact with anything.

2. Press the left side button ("Start"). "BLANK STRIP" appears.

3. When ">>PUSH DIPSTICK OUT>>" appears, place the calibration strip, with the test window facing upwards and out with the sample-tearing window.

ATTENTION: It is very important that the blank Dipstick locks into the instrument correctly in order to ensure the quality of the calibration

4. Equipment set the correct lighting. An acknowledging beep sounds. Remove the blank Dipstick. It may use for an hour yet to normal measure.

6.2 Sample preparation and application

Follow instruction in: KIT INSTRUCTIONS
Doc: TWINSENSOR / V1.6 (*or upgraded)*.

This document is provided with each kit.

CAUTION: There are a few aspects that should be kept in mind during measurements:

- **The reaction time has to be kept accurately.**
- **The correct test dipstick positioning is essential, the dipstick must be planar with both top and bottom part included in the furrow of the rapid designer. Some dipstick might be a bit large or small and you should regard this as a major when loading the dipstick on the furrow.**
- **There are some disturbing effects that the reader itself cannot detect. The reader can not distinguish big scratches from coloration, thus strips with such defects should not be measured or the measurement result has to be used cautiously.**

ATTENTION: To ensure that Readsensor is carried out correctly, read the package insert included with the test strip.

If the Dipstick was already inserted, "<<PULL DIPSTICK OUT<<" message appear on LCD. The Dipstick has to be removed and reinserted, the reader does not accept any strip already residing in the optics at the start of any measurement. In the other case ">>PUSH DIPSTICK IN>>" message displayed on LCD. Insert the Dipstick into the slot of the optics with a single continuous movement. **If the strip is stopped during its course for a longer period of time (1-2 seconds) the reader might start the measurement.** Such operation could lead to false readings despite of the thorough measurement validity checks that the reader performs during result evaluation. When the reader accepts the strip as stabilized it starts the measurement procedure indicated by *READING IN PROGRESS* in the first line of the display. After a few seconds the result is evaluated and is printed on paper and on demand line-by-line on the LCD screen. If the reader does not accept the strip as a valid test strip (e.g.: missing control, reference line, or test redrawn during measurement) *E06: STRIP INVALID* error message will be displayed.

5. When ">>PUSH DIPSTICK IN >>" appears, place the Dipstick, with the test window facing upwards and out with the specimen-tearing window.

6. When Dipstick is measured, calculating the result and print and/or send it.

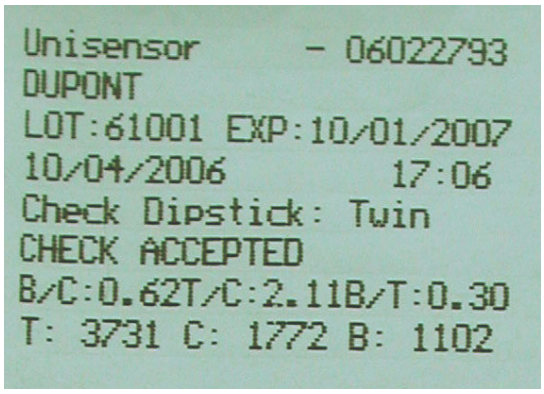
7. Selecting the "Measure" menu point to take another measure.

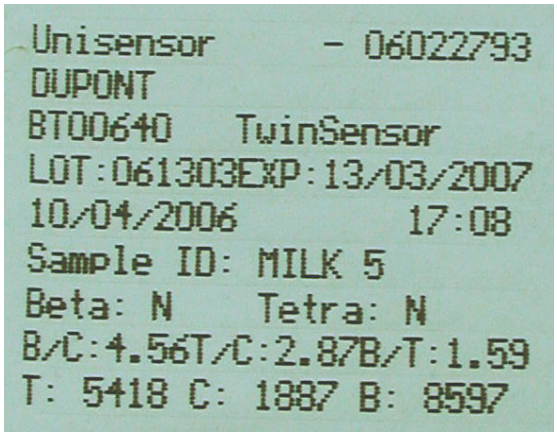
After the completion of a measurement a new one can be initiated by selecting the "Measure" menu. This will restart the measurement procedure.

6.3 Result Report

The result report is printed out together with the sequence number, date and time. The sample's name may be entered manually on the printout. If a sample's ID was entered in advance of the reading (see Section 6.2), it will be printed out together with the sequence number.

The reports are printed out in the following form.





6.4 Strip Measurement Error

If any error message appears during the measure, the test strip and/or analyzer have probably been incorrectly used. Refer to Section 8 for details.

7 Interpretation of Results

The Readsensor gives results in a qualitative form, which means in 3 ranges. One NEGATIVE, one LOW POSITIVE and one POSITIVE.
These are the following:

For Twinsensor:	POS	when TEST / CTRL (B/C or T/C) =< 0.9
	LOW POS	when 0.9 < TEST / CTRL =< 1.1
	NEG	when TEST / CTRL (B/C or T/C) > 1.1
For Tetrasensor:	POS	when T/C =< 0.95
	LOW POS	when 0.95 < T/C =< 1.3
	NEG	when T/C > 1.3

For the visual interpretation of the measurement results, please, refer to the User's Manual of the Test Dipstick.

8 Cleaning and Maintenance

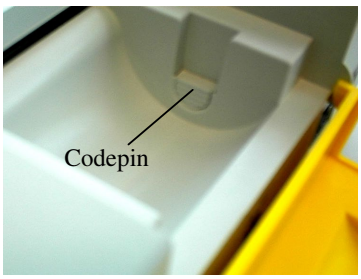
Readsensor is designed for maintenance-free operation. Protect the instrument from extremes of temperature and high atmospheric humidity (see Section 10), and keep it out of bright light (direct sunlight, spot lamps, etc.).
Maintain hygiene by keeping the exterior parts and surfaces of the instrument clean. For cleaning apply a commercial cleaning agent or disinfectant (preferably 70 % alcohol) with a moist cloth. Take care that no liquid enters the instrument.

9 Error and warning messages

The Readsensor has an intelligent error detecting system to minimize the error of the routine test. In case of an error, together with an audible signal and the blinking of the LED in red, a message appears on the display. An error / warning message consists of an error code and a short text refers to the source of the error.
In case of the error messages the reader stops its functional working, what can be continued only after the action of the user.
In case of the warning messages the reader pauses its functional working for the short period of the warning and steps back automatically to the previous screen.

The possible error and warning messages, the possible causes and troubleshooting are detailed in the following:

E04: WRONG CODEKEY
The chip module on the left of the analyzer underneath the printer cover is not valid or damaged. Check the codepin and change to a proper one.



E05: NO CODEKEY
The electronic codepin is not correctly inserted. Insert the codepin correctly.
If the error persists, withdraws the codepin delicately, cleans the contactors and introduces again delicately.

E06: STRIP INVALID
The measured strip is not valid. No test strip is present or the Dipstick is incorrectly positioned, control line did not develop properly or a test strip different from the set one is used. The test strip was removed during the measurement.
Press **Next** button to carry out a measurement again. Change the test strip to a proper one.

E10: WRONG POSITION
The strip is not properly placed.
Check the position of the strip.

E11: WRONG LOT NUMBER
Either the wrong LOT number was entered or the codekey was replaced while the reader was on.

E20: WRONG DATE
An invalid date was entered.
Check the date and enter the valid one.

E22: CALIBRATION ERROR
The reader was not able to carry out the calibration.
Repeat the calibration again, taking care of all the details.

E23: PRINTER ERROR
Printing failure because of the stucked paper. Switch off and clear the stucked paper, if there is one. Switch the analyzer on again. If the error message appears again, the instrument is defective.

E25: EXTERNAL LIGHT
An external light is affects the measured area of the Dipstick.
Do not expose the slut of the optic system to bright and direct light.

E28: BLANK / OPTIC FAULT
During the blank calibration, the calibration strip is not smooth enough or it has some scratches / coloration at the lines position and the optic system get soiled.
Check the blank Dipstick that there is not any coloration or soil and clean the inside mirror.

VALUES OBTAINED ARE IMPLAUSIBLE WHEN, COMPARED WITH THOSE FROM VISUAL EVALUATION
Test Dipstick incorrectly positioned, proper incubation intervals not kept. Electromagnetic interference from other devices (see Section 4)
Repeat the measurement with a new Readsensor Test Dipstick. Follow the directions carefully and ensure the test Dipstick is correctly inserted. Repeat calibration if necessary (after switch off/on). Remove external sources of interference, if there are any.

NO PRINTOUT
"Printer: Off has been selected, or the printer/software is defective, or the printer is out of paper. Insert paper if needed. Choose "Printer: On" to re-activate the printer. Request a patient report via the "Print" function. If this fails, activate the "Linefeed" function. If there is still no response, the instrument is defective.

10 Connecting to Other Devices

10.1 RS 232 Serial Interface

The RS 232 serial interface - through which it can be connected to PC – is located at the rear side of the Readsensor. If requested, Unisensor SA. supplies appropriate standard data cable for data transfer between the Readsensor and host PC. Connected PC must satisfy the electrical safety requirements laid down in EN 60950. The protocol is unidirectional, with the following parameters:

9600 Baud
8 databits
No parity
1 stopbit

Data cable: D-sub, 9-pin, male on instrument side, female on PC side.
Connections:

1		1
2——	RxD ——	2
3——	TxD ——	3
4——	DTR ——	4
5——	GND ——	5
6		6
7		7
8		8
9		9

Records stored in the memory can be transmitted from the Readsensor to PC. That is how old measurements can be archived on host PC. On PC side only a serial terminal program is needed for successful data transfer. Any kind of serial terminal program can be used. The manufacturer recommends the use of Hyperterminal, which is supplied with every Windows operating system.

CAUTION: Use of data cable not meeting the specification of the manufacturer may damage the Readsensor or may result data loss.

10.2 AT/PC Keyboard

User address, Sample or Patient IDs can be entered via an AT/PC keyboard. Power is supplied by the PS2 interface.
Interface specification: 6-pin PS2 socket, female
Pinouts:

1. data
2. n/c
3. GND
4. +5V
5. clock
6. n/c

11 Technical Information and Notices

11.1 Technical Data

Dimensions:	Width:	195 mm
	Depth:	200 mm
	Height:	75 mm
	Weight:	785g
	Power supply:	External mains adapter, Model SA125A-0735U-S (Sino-American)
	Input: 100-240 V AC, 50/60 Hz	
	Output: 7.5 V DC, 3000 mA	
Consumption:	Operating: max.3 Watt	
System description:	Type: reflectance photometer	
	Light source: LEDs (light emitting diodes)	
	Wavelengths:	528 nm (green)
	Reader head:	CCD with a 320*90 useful resolution
	Sample:	80 µl capillary blood or serum (two drop of regular volume)
	Measuring and displayed range:	<3ng/ml 3-5ng/ml 5-10ng/ml 10-20ng/ml >20ng/ml
	Measuring cycle:	approx. 60 sec (serial measure)
	Max. throughput:	60 Dipstick/hour (serial measure)
	Printer:	thermal printer
	Display:	liquid crystal display, 2 lines of 24 characters
	Memory:	26 samples
	Date, time:	integrated clock

Operating / Storage conditions:	In operating	In storage
Temperature:	+15 ° to + 30 °C	-20 ° to + 70 °C
Relative humidity:	20 % to 80 %	20 % to 85 %

Optimum operating conditions:

Temperature:	+ 20 ° to + 26 °C
Relative humidity:	30 % to 60 %

Interfaces:

PC/HOST:	RS 232, D-Sub socket, 9-pin, female, unidirectional
AT/PC keyboard:	6-pin PS2 socket, female

11.2 Safety Notices

Readsensor meets the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices. Furthermore, this analyzer was designed and manufactured to comply with international standard IEC 1010-1, "Safety requirements for electrical equipment for measurement, control and laboratory use, part 1: general requirements" and left the factory in a safe condition. This international standard is equivalent to the standards UL 3101-1 for the USA, CSA C22.2 No. 1010.1 for Canada and EN 61010-1 for EU.

The Readsensor fulfils the requirements of the EMC Directive on electromagnetic compatibility.
This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

In order to keep your instrument in a perfect and safe condition, it is up to the user to observe all instructions and warnings included in this manual.
The instrument must only be operated with the prescribed power supply unit (Class II protection).

Opening covers or removing parts of the instrument, except where this can be achieved manually without the use of any tools, may expose voltage-carrying components. Connectors can be live, too. Never try to maintain or repair an open instrument, which is carrying voltage.

If you suspect that the instrument can no longer be operated safely, turn it off and take steps to ensure that no one will subsequently attempt to use it. Make sure that only trained members of staff operate the Readsensor analyzer.
Any personal computer to which the analyzer is connected must meet the EN 60950 requirements for data processing equipment.

ATTENTION: The data and information contained in this manual are accurate at the time of going to press. Any substantial changes will be incorporated in the next edition. In case of conflict between this manual and information given in package inserts, the package inserts shall take precedence.

11.3 Manufacturer's Warranty

Unisensor SA. warrants Readsensor against defects in materials and workmanship for a period of one year from the date of purchase. The warranty ceases to apply if the instrument has been misused, poorly maintained or tampered with. Liability under this warranty is limited to the repair of defective parts or, at the discretion of Unisensor SA., to the issue of a replacement instrument. A right to rescind the purchase agreement only exists if the replacement instrument is also found to be defective. Claims other than these will not be entertained.
Damage caused by misuse, maltreatment, tampering, human error and extreme force are excluded from this warranty.
This warranty is only valid if the date, and the stamp and signature of the dealer are entered on the warranty card on the date of purchase.
The warranty period is not extended by any claim made under this warranty.

Readsensor developed for Unisensor SA. By :

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IVD	for professional use
REF	RAC-9903-1
CE	

The following symbols are used throughout this document

Symbols/Signs	**Explanation**
	WARNING/CAUTION: Indicates a potentially hazardous situation that if not avoided could result in personal injury or damage to the instrument. This symbol is also used to highlight situations that can compromise results.
	BIOHAZARD: Indicates a potentially dangerous situation involving the presence of biohazardous material. All safety precautions must be taken to prevent personal injury or damage to the equipment.
	ATTENTION: Indicates special problems or important information. Read the accompanying text carefully.
IVD	In Vitro Diagnosticum
CE	98/79/EC IVD directive, **Readsensor** equipment
	Consult instructions for use
SN	Serial No.
	Manufacturer
REF	Catalog No.

Service Records:

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